K012495 OCT 31 2001

10 Appendix: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information.

Establishment:

- Address: Siemens Medical Systems, Inc.
  186 Wood Avenue South
  Iselin, N.J. 08830

Registration Number: 2240869

Contact Person: Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
Phone: (732) 321-4625
Email: jamie.yieh@sms.siemens.com
Fax: (732) 321-4841

Date of Summary Preparation: 8/2/01

Device Name:

•Trade Name: OR Table and Headholder with the MAGNETOM Harmony, Symphony, Sonata

•Classification Name:
Magnetic Resonance Diagnostic Device, CFR § 892.1000

•Classification: Class II

•Performance Standards:
None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

• Device Description:

•Intended Use

The MAGNETOM Harmony, Symphony, and Sonata System with the OR Table and Headholder is a whole body scanner. The MAGNETOM Systems with the OR Table and Headholder is indicated for use as diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by MAGNETOM Systems with the OR Table and Headholder reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The OR Table with headholder will be an option for intra-operative and interventional procedures.

• Technological Characteristics

The MAGNETOM Harmony, Symphony, Sonata with the new OR Table and Headholder is substantially equivalent to the Neuro II system.

• General Safety and Effectiveness Concerns:

The introduction of the new OR Table and headholder has no significant effect on the following MR safety and performance parameters:

[Safety]

- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]

- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

Since we are simply adding an optional OR Table and headholder to the already existing MAGNETOM Harmony, Symphony, Sonata system, which will have exactly the same components (i.e. magnet, gradients, RF, and operating software). The optional OR Table and headholder will not have any significant effect on the currently available systems. The OR Table and headholder will be used in various applications ranging from regular diagnostic scans to interventional/intra-operative procedures. To ensure that the OR Table or headholder does not influence the MAGNETOM

Harmony, Symphony, Sonata, Siemens did an evaluation on interference from the OR table which could affect the safety or effectiveness with the currently available systems.

• **Substantial Equivalence:**
Laboratory testing were performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K012495
Trade/Device Name: OR Table and Headholder for MAGNETOM Harmony, Symphony Sonata
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: August 2, 2001
Received: August 3, 2001

Dear Mr. Yieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K012495

Device Name: OR Table and Headholder for MAGNETOM Harmony, Symphony, and Sonata Systems

Indications for Use:

The MAGNETOM Harmony, Symphony, and Sonata System with the OR Table and Headholder is a whole body scanner. The MAGNETOM Systems with the OR Table and Headholder is indicated for use as diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by MAGNETOM Systems with the OR Table and Headholder reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The OR Table with headholder will be an option for intra-operative and interventional procedures.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use____

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012495